Remarks

Upon entry of the foregoing amendment, claims 20 and 22-28 are pending in the application, with claims 20 and 24-28 being the independent claims. Claims 19 and 21 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Support for the amendments in claims 20 and 22-26 can be found on page 5 of the specification, as well as in Figure 4. Support for new claims 27 and 28 can be found on page 26.

Objections to the Specification

In the Office Action, at page 2, the Examiner objected to the lack of sequence identifiers for the amino acid and nucleic acid sequences contained in Figure 1. Applicants have amended the specification, in accordance with the Examiner's suggestion, to include the proper sequence identifiers in the brief description of Figure 1.

In the Office Action, at page 2, the Examiner noted the use of the trademark SEP-PAK in the specification. In accordance with the Examiner's suggestion, Applicants have amended the specification to clearly identify this trademark as such.

Rejections under 35 U.S.C. § 112

In the Office Action, at page 3, claims 19-26 were rejected under U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Applicants canceled claims 19 and 21, thus rendering their rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims.

Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have amended the claims in accordance with the Examiner's

suggestion by reciting "determining whether said test compound is an agonist or an antagonist of PTH receptor activity" in claims 20 and 22-26. Therefore, this aspect of the rejection is overcome.

In the Office Action, at page 3, claims 19, 20 and 22-26 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner objected to the phrase "biological response" and stated that "[o]ne skilled in the art would not know what the metes and bounds of a 'biological response' are." Applicants have cancelled claim 19, thus rendering its rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims. Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have amended the claim to recite "measuring cAMP accumulation" in claims 20 and 22-26.

In the Office Action, at page 4, claims 20-26 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Specifically, the Examiner stated that it is not clear that the novel cDNA clone deposited as ATCC Deposit No. PGA-1136 was deposited under the Budapest Treaty or when it was deposited. By the forgoing amendment, Applicants have indicated that the cDNA clone was deposited on December 28, 1999. Applicants also herewith file an affidavit by Dr. Thomas J. Gardella, a co-inventor of the present invention, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

In the Office Action, at page 6, claims 19, 20, and 22-26 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. Specifically, the Examiner stated that "the specification, while being enabling for a method of screening for agonists or antagonists of a polypeptide by measuring the amount of cAMP accumulation, does not reasonably provide enablement for a method of screening for agonists or antagonists of a polypeptide by measuring any biological response."

Applicants have cancelled claim 19, thus rendering its rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims. Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have amended the claim to recite "measuring cAMP accumulation" in claims 20 and 22-26.

In the Office Action, at page 7, claims 20-24 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of screening for agonists or antagonists of a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, allegedly does not reasonably provide enablement for a method of screening for agonists or antagonists of polypeptides that are 95% identical to SEQ ID NO: 2.

Applicants have cancelled claim 21, thus rendering its rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims. Applicants note that they are not required to provide experimental examples of each and every polypeptide that would fall under the scope of the claims. *See, e.g., Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1237, quoting *In re Angstadt,* 537 F.2d 498, 502, 190 U.S.P.Q. (BNA) 214, 218 (CCPA 1976) ("it is not necessary that a patent applicant test all the embodiments of his invention. . . . what is necessary is that he provide a disclosure

sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims."). Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have amended the claims to make explicit that which was implicit. Thus, Applicants have added the phrase "wherein said polypeptide has substantially identical structure and function to the structure and function of a rδNt receptor" to further characterize the claimed methods.

In the Office Action, at page 7, claims 20-24 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Specifically, the Examiner stated that claims 20-24 are drawn to a genus, i.e., a method of screening for agonists or antagonists of proteins of at least 95% identity to SEQ ID NO: 2 and that Applicants have disclosed one species, a method of screening for agonists or antagonists of the polypeptide of SEQ ID NO: 2, but have not disclosed sufficient species for the broad genus which encompasses any protein at least 95% identical to SEQ ID NO: 2.

Applicants have cancelled claim 21, thus rendering its rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims. Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have added the phrase "wherein said polypeptide has substantially identical structure and function to the structure and function of a rδNt receptor" to further characterize the claimed compounds.

Applicants respectfully draw the Examiner's attention to pages 20-24 of the specification. In those pages, Applicants have provided an ample and sufficient description of the types of substitutions that can be made in the rδNt polypeptide according to the present invention. Because these substitutions will result in a polypeptide that is substantially similar

in function to the polypeptide of SEQ ID NO: 2, screening for agonists or antagonists with these polypeptides will be functionally identical to screening for agonists or antagonists with the polypeptide of SEQ ID NO:2. Therefore, Applicants respectfully submit that these disclosures amply satisfy the written description requirement.

In view of the foregoing amendments, Applicants respectfully request that the rejections of claims 20 and 22-26 under 35 U.S.C. § 112 be withdrawn.

Rejections under 35 U.S.C. § 102

In the Office Action, at page 9, claims 19-24 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,494,806 ["the '806 patent"]. Specifically, the Examiner stated that the '806 patent teaches methods of screening for antagonists or agonists of PTH receptors by contacting cells expressing a PTH receptor with a test compound and measuring cAMP accumulation. Further, the Examiner stated that the '806 patent teaches the nucleic acid sequence and amino acid sequence of rat PTH receptor which is 96.1% identical to SEQ ID NO:2.

Applicants have cancelled claims 19 and 21, thus rendering their rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims. In certain aspects, the present invention relates to methods of screening for agonists or antagonists of the rδNt receptor, a mutant variant of the wildtype PTH1R receptor. One of the features that distinguishes the rδNt receptor from the wildtype PTH1R receptors that were identified previously is the lack of a domain that corresponds to the extracellular amino-terminal ligand binding domain of the wildtype PTH1R receptor. Thus, although the rδNt receptor is highly homologous to the wildtype PTH1R receptor in the domains that the two

receptors have in common, this deletion makes it both structurally and functionally distinct. Applicants have clarified this distinction by amending the claims to recite the phrase "wherein said polypeptide comprises a deletion of the extracellular amino-terminal ligand binding domain of a PTH-1 receptor, said extracellular amino-terminal ligand binding domain having an amino acid sequence from about 26 to about 181 in wild-type PTH receptor" to describe the rδNt polypeptide.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. See Kalman v. Kimberly Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984); see also PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996) ("[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."). In addition, under 35 U.S.C.§102(b), a claim can only be anticipated by a publication if the publication describes the claimed invention with sufficient detail to place the public in possession of the invention. See In re Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985). Applicants respectfully submit that the '806 patent does not disclose the rδNt mutant receptor, which is a key feature of the present invention. Because the '806 patent does not disclose a key feature of the invention claimed in the above-captioned application, Applicants respectfully assert that it does not support a rejection of the invention as presently claimed under 35 U.S.C.§102(b).

In the Office Action, at page 10, claim 19 was rejected under 35 U.S.C.§102(e) as being anticipated by U.S. Patent No. 6,495,662. By the foregoing amendment, Applicants have cancelled claim 19, thus rendering its rejection moot.

In view of the foregoing amendment and explanation, Applicants respectfully request that the rejections under 35 U.S.C.§102 be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Date: Sept 20, 2004

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